



Guidelines for Security Printer Policies and Procedures **(Health & Safety Code sections 11161.5 and 11162.1 et seq.)** **Revised 3/05**

Under California law, security printer applicants must have policies and procedures that address four general areas. A copy of your policies and procedures must be submitted with your application for approval, as a designated security printer, to produce controlled substance prescription forms.

The following methods and criteria are provided for your review to assist you in writing policies and procedures that meet or exceed the requirements of California law:

1) Prescriber Identification and Verification of Prescribing Privileges

Policies and procedures for verifying the identity of the prescriber ordering controlled substance prescription forms. Before printing any controlled substance prescription forms a security printer shall verify with the appropriate licensing board that the prescriber possesses a license and current prescribing privileges, which permits the prescribing of controlled substances. (Health & Safety Code section 11161.5, subdivisions (b)(2), & (f))

▪ State Practitioner License Verification

License verification of the prescriber can be accomplished online, free of charge, by visiting www.dca.ca.gov. Click on the "License and Complaint History" icon, and then choose the prescriber's license type (i.e., physician under Medical Board, dentist under Dental Board etc.). Another option is to order a monthly list of current licensees for each of the prescriber boards, in either hard copy or as a data file, through the Department of Consumer Affairs, Public Sales Office by calling (916) 323-7018. There is a fee for this service. Regardless, security printers are required to verify that the prescriber license is not expired or otherwise restricted and make a record that these items have been verified.

State license verification for all prescribers listed on the prescription form must occur with each order, every time, even repeat orders. The "License Status" must indicate Clear, Renewed/Current, or Active. However, clear, renewed/current or active licensees may also have limitations on prescribing privileges. In this case, the license may indicate clear, renewed/current, or active but there will be secondary status information such as, Probation, Limits on Practice, Suspended, etc. The record may also indicate a "yes" under Public Record Actions. If a license indicates anything other than clear, renewed/current, or active, the security printer must call the applicable licensing board below for verification the licensee is permitted to practice and write controlled substance prescriptions.

Dentists	Dental Board of California	916-263-2300 ext. 2328
Nurse Practitioners and Certified Nurse Midwives	Board of Registered Nursing	916-324-2715 ask for nursing education consultant
Optometrists	Board of Optometry	916-445-8663
Osteopathic Physicians	Osteopathic Medical Board	916-263-3100
Physician Assistants	Physician Assistant Committee	916-263-2670
Physicians and Surgeons	Medical Board of California	916-263-2499 or 916-263-2644
Podiatrists	Board of Podiatric Medicine	916-263-2647
Veterinarians	Veterinary Medical Board	916-263-2610 or 916-263-2617

▪ Authority to Prescribe Controlled Substances (DEA Registration)

The security printer must also check the prescriber's authority to write controlled substance prescriptions. Prescribers must register with the Drug Enforcement Administration (DEA) and obtain a DEA Registration number before they can write controlled substance prescriptions. The security printer must obtain a copy of the DEA registration of every prescriber preprinted on the prescription form. A copy must be obtained with every order, even repeat orders. As an alternative to obtaining a copy from the prescriber, the security printer can purchase a monthly subscription to the DEA

registration database and print a copy from the database or save an electronic record. Security printers may order a subscription to the DEA registration database by visiting the Drug Enforcement Administration's website at <http://www.ntis.gov/products/types/dea/index.asp?loc=4-4-1>. There is a fee for this service.

In either case, security printers must check the DEA registration to ensure it is not expired, the prescriber is authorized to write a controlled substance prescription (Schedule 2, 2N, 3, 3N, 4 and/or 5), that the name on the registration matches what will be printed on the prescription form, and make a record that these items have been verified.

2 Verification of Delivery to Prescriber and Proof of Such Delivery to the Printer

Policies and procedures of the applicant for verifying delivery of controlled substance prescription forms to prescribers. Controlled substance prescription forms shall be provided directly to the prescriber either in person, by certified mail, or by means that requires a signature signifying receipt of the package and provisions of that signature to the security printer. (Health & Safety Code section 11161.5, subdivisions (b)(3), & (g))

Delivery of controlled substance prescription forms must be in person, via certified mail, or some other means where a signature is required upon delivery and a return receipt showing proof of that delivery is automatically sent back to the security printer. This proof of delivery record must be kept for three years.

Note: Online proof of delivery verification is acceptable but please verify with the carrier that the records are available online for a full three years; otherwise, a hard copy must be printed and kept in the file. Please see item #3 below.

3) Records Retention

Policies and procedures for the retention of ordering and delivery records in a readily retrievable manner for individual prescribers for three years. (Health & Safety Code section 11161.5, subdivision (h))

Procedures should describe the documents that will be retained for three years (e.g., order forms, production orders, tracking documents including batch/lot numbers, copies of DEA registration, proof of delivery from carrier, shipping documents, form templates, artwork, etc.) and in what format the documents will be retained (hard copy or electronic). Hard copy and electronic documents should be stored in such a way to prevent loss from unforeseen disaster such as fire or flood. They should also be stored in locked facilities or cabinets. Electronic documents should be backed up onto disk or CD. Form templates must be password protected with limited access. The records must be in a readily retrievable format for law enforcement. For example, law enforcement may inquire about the sale of prescription forms to a particular doctor over the past year. How quickly can this information be provided to law enforcement, and what documents will be provided? Please provide a contact name, phone number, address, and business houses for law enforcement to contact to obtain copies of the records.

4) Production and Distribution of Controlled Substance Prescription Forms

Adequate security procedures relating to the production and distribution of controlled substance prescription forms. (Health & Safety Code section 11161.5, subdivision (d)(5))

- a) The security printer must have the facilities and specialized equipment necessary to apply all of the security features required in Health & Safety Code section 11162.1 et seq., to produce the new controlled substance security prescription forms. **Security printers may not purchase stock paper with pre-applied security features and/or prescription format and simply print prescriber information.** Security printers can purchase completely blank (unformatted) stock

paper that already incorporates the latent repetitive void pantograph and/or the chemical void protection **only**. However, the board would prefer approved printers to apply all security features in-house.

Note: Printers are cautioned not to offer for sale to anyone, even to an approved printer, preformatted and/or blank stock paper, or laser, dot matrix, or thermal printer paper that includes all or most of the security features required by Health and Safety Code section 11162.1 et seq. A plain stock, laser, dot matrix, or thermal paper with no more than the latent repetitive void and/or the chemical void protection is permitted for sale. However, the paper may include other non-required security features such as red fiber paper, etc., if desired to exceed the requirements.

- b) The security printer will offer, at a minimum, the three (3) basic prescription form styles (one drug per prescription, multiple drugs per prescription, and an institutional style form) listed in Health and Safety Code section 11162.1 subdivision (a) paragraph (8) and subdivision (c). More information can be found on our website at www.pharmacy.ca.gov.
- c) If your company will be using distributors to market your product, your policies and procedures should address the ordering process and distributor's responsibilities. The approved security printer is always responsible for retaining all related ordering, production, and delivery records for 3 years; therefore, policies and procedures should specify the documents you will require from your distributors, as well as the format desired, the expected timeframe, and the desired method for receiving the documents. The board recommends a formal agreement that clearly identifies expectations and responsibilities, and includes instructions that any advertising by the distributor indicates they are an authorized distributor for your products. Distributors may not advertise that they themselves are an approved security printer.

The board no longer lists authorized distributors on the board's website. Instead, approved security printers using distributors must develop and maintain a website of their own that provides the name, address, and contact information for each of their authorized distributors. Please email the link or website address to Security_Printer@dca.ca.gov so that the link can be added under your contact information on our "Approved Security Printer" website, upon approval.

Security printers are responsible for establishing and maintaining effective controls and security procedures to prevent loss or theft of raw materials used to make controlled substance prescription forms, as well as, partially finished and finished forms. The following elements may apply and should be addressed in your policies and procedures relating to the production and distribution of controlled substance prescription forms. However, some elements may not apply to your specific business structure:

- d) Secure production and storage facilities (i.e., alarm systems, vaults, locked cabinets and storage facilities, security guards, security cameras, card key ID access, etc.)
- e) Accountability and tracking procedures at all phases of product development, storage, and distribution. (Limited access to keys, raw materials, form templates, and stored finished and partially finished product, electronic tracking systems, secure transport between security printer facilities, minimize access to raw materials and finished product. Ink supplies and form templates are housed in locked facilities and keys are secured. Restricted access to all visitors, etc.)
- f) Procedures for the destruction of discarded or waste materials during production. Procedures for the pickup, recording batch/lot numbers, and destruction of all returned product from customers. Loss/theft in transit must be reported to local law enforcement and the Bureau of Narcotic Enforcement at (916) 319-9062.

- g) Use of discrete shipping cartons to minimize potential theft.
- h) Database, network, and internet systems have updated firewalls and virus protection in place to prevent electronic breach of confidentiality of information captured during the telephonic and online product ordering, tracking, storage, distribution, destruction etc. Artwork/templates are password protected with limited access.
- i) Policy for internal investigation if an employee is suspected of or found to be tampering with or stealing raw materials, or finished or partially finished product. Include that you will contact the Bureau of Narcotic Enforcement at 916-319-9062 and local law enforcement. Include steps to prevent future incidents. Forms or raw materials lost in transit should also be reported to authorities.
- j) Operational recovery and business continuity plans in place in case of unforeseen disaster or disruptions. Are data files backed up regularly? Are hard copy documents safeguarded from fire/flood? Any hardcopy or electronic files kept offsite must be secured with limited access.
- k) Please include a statement that as an approved security printer, you will: (1) submit annually the location, name, and title of the company's agent for service of process in California; and (2) submit within 30 days after any change of offices, principal corporate officers, or managing general partners.